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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,146	01/25/2002	Victor C.W. Tsang	6395-62068	8734

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/048,146	TSANG ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,17-23,27 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,17-23,27 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *070704*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

1) Acknowledgment is made of Applicants' amendment filed 08/16/04 in response to the non-final Office Action mailed 04/15/04.

Status of Claims

2) Claims 2, 4, 24-26 and 28 have been canceled via the amendment filed 08/16/04.

New claim 29 has been added via the amendment filed 08/16/04.

Claims 1, 3, 5, 18, 20, 21, 23 and 27 have been amended via the amendment filed 08/16/04.

Claims 1, 3, 5, 17-23, 27 and 29 are pending and are under examination.

Declarations

3) Acknowledgment is made of Applicants' submission of the two Declarations filed 08/16/04 under 37 C.F.R § 1.131 and the Hancock and Tsang Declaration filed 08/16/04 under 37 C.F.R § 1.132. The Declarations have been considered as described below.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Moot

6) The rejection of claims 2 and 4 made in paragraph 10(a) of the Office Action mailed 04/15/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

7) The rejection of claims 2 and 4 made in paragraph 14 of the Office Action mailed 04/15/03 under 35 U.S.C. § 102(a) as being anticipated by Greene *et al.* (*Mol. Biochem. Parasitol.* 99: 257-261, 30 April 1999 - Applicants' IDS) (Greene *et al.*, 1999), is moot in light of Applicants' cancellation of the claims.

8) The rejection of claim 4 made in paragraph 15 of the Office Action mailed 04/15/03 under 35 U.S.C. § 102(e)(2) as being anticipated by Doucette-Stamm *et al.* (US 6,583,275, filed 07/02/1997) as evidenced by Greene *et al.* (*J. Parasitol.* 86: 1001-1007, 2000 – Applicants' IDS)

(Greene *et al.*, 2000), is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

9) The rejection of claims 23 and 27 made in paragraph 10(a) of the Office Action mailed 04/15/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

10) The rejection of claim 5 made in paragraph 10(b) of the Office Action mailed 04/15/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.

11) The rejection of claim 21 made in paragraph 10(c) of the Office Action mailed 04/15/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.

12) The rejection of claim 23 made in paragraph 10(e) of the Office Action mailed 04/15/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.

13) The rejection of claims 1 and 20-22 made in paragraph 12 of the Office Action mailed 04/15/03 under 35 U.S.C. § 102(a) as being anticipated by Hubert *et al.* (*Clin. Diagn. Lab. Immunol.* 6: 479-482, July 1999 - Applicants' IDS), is withdrawn in light of Applicants' amendments to the claims and/or the base claim.

14) The rejection of claims 1, 2 and 27 made in paragraph 13 of the Office Action mailed 04/15/03 under 35 U.S.C. § 102(b) as being anticipated by Tsang *et al.* (US 5,354,660 – Applicants' IDS), is withdrawn in light of Applicants' amendments to the claims and/or the base claim.

15) The rejection of claims 1, 3, 5 and 27 made in paragraph 14 of the Office Action mailed 04/15/03 under 35 U.S.C. § 102(a) as being anticipated by Greene *et al.* (*Mol. Biochem. Parasitol.* 99: 257-261, 30 April 1999 - Applicants' IDS) (Greene *et al.*, 1999), is withdrawn in light of Applicants' submission of the Rule 131 Declaration showing that the reference is not the work of another.

16) The rejection of claims 17 and 20-22 made in paragraph 17 of the Office Action mailed 04/15/03 under 35 U.S.C. § 103(a) as being unpatentable over Hubert *et al.* (*Clin. Diagn. Lab. Immunol.* 6: 479-482, July 1999 - Applicants' IDS), or Tsang *et al.* (US 5,354,660 – Applicants' IDS), or Greene *et al.* (*Mol. Biochem. Parasitol.* 99: 257-261, 30 April 1999 - Applicants' IDS)

(Greene *et al.*, 1999) as applied to claim 1 and further in view of Campbell AM (*In*: *Monoclonal Antibody Technology*. Elsevier Science Publishers, The Netherlands, Chapter 1, pages 1-32, 1984), is withdrawn in light of Applicants' amendment to the base claim, Applicants' arguments and/or Applicants' submission of the Rule 131 Declaration showing that the reference of Greene *et al.* is not the work of another.

17) The rejection of claims 18 and 19 made in paragraph 18 of the Office Action mailed 04/15/03 under 35 U.S.C. § 103(a) as being unpatentable over Hubert *et al.* (*Clin. Diagn. Lab. Immunol.* 6: 479-482, July 1999 - Applicants' IDS), or Tsang *et al.* (US 5,354,660 – Applicants' IDS), or Greene *et al.* (*Mol. Biochem. Parasitol.* 99: 257-261, 30 April 1999 - Applicants' IDS) (Greene *et al.*, 1999) as applied to claim 1 above, is withdrawn in light of Applicants' amendment to the base claim, Applicants' arguments and/or Applicants' submission of the Rule 131 Declaration showing that the reference of Greene *et al.* is not the work of another.

Rejection(s) Maintained

18) The rejection of claim 23 made in paragraph 10(d) of the Office Action mailed 04/15/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Claim 23, as amended, still lacks proper antecedent basis in the recitation 'SEQ ID NO: ...'. Claim 23 depends from claim 3, which already recites 'SEQ ID NO: 4'. Therefore, for proper antecedence, in line 1 of amended claim 23, it is suggested that Applicants replace the recitation 'SEQ ID N: 4' with --said SEQ ID NO: 4--.

19) The rejection of claims 1, 5 and 17-21 made in paragraph 15 of the Office Action mailed 04/15/03 under 35 U.S.C. § 102(e)(2) as being anticipated by Doucette-Stamm *et al.* (US 6,583,275, filed 07/02/1997) as evidenced by Greene *et al.* (*J. Parasitol.* 86: 1001-1007, 2000 – Applicants' IDS) (Greene *et al.*, 2000), is maintained for reasons set forth therein and herebelow.

Applicants submit a Rule 131 Declaration and contend that they cloned and invented the amino acid sequence IAQLAK prior to Doucette-Stamm's filing date of 30 June 1998. Applicants submit a dateless Exhibit B containing the peptide sequence data allegedly obtained prior to June 30, 1998 from a sample submitted to Harvard MicroChem for sequencing. Applicants state that they have not been able to determine if it is necessary to swear behind the related Doucette-Stamm's provisional applications, 60/085,598 filed 14 May 1998 and 60/051,571 filed 02 July

1997. Applicants allege that they were not provided with a copy of these applications, and that the Office has not met the burden of establishing that Doucette-Stamm *et al.* is entitled to a priority date earlier than the 30 June 1998 date of the non-provisional application. Applicants state that these provisional applications are not readily available to Applicants and request the Office to provide a copy of the corresponding provisional applications if the Office intends to assert that these provisional applications disclose the IAQLAK peptide at issue. Applicants further allege that the Office has not established a *prima facie* case of anticipation.

Applicants' arguments and the Rule 131 Declaration have been carefully considered. First, it is noted that Applicants do not deny that Doucette-Stamm *et al.* disclosed a composition comprising the IAQLAK sequence, i.e., the instantly recited SEQ ID NO: 7. With regard to Applicants' allegation that a *prima facie* case of anticipation has not been established because the Office did not provide Applicants with a copy of the provisional applications, the following should be noted. The provisional applications, 60/051,571 and 60/085,598, are very voluminous applications containing thousands of pages. The Office has terminated the practice of supplying a copy of a provisional application(s) relied upon to give prior art effect under 35 U.S.C. § 102(e) to a reference applied in a rejection. However, Applicants are referred to the Public PAIR website at http://portal.uspto.gov/external/portal/pair for viewing and/or printing the provisional applications. If Applicants cannot view or print the provisional applications from the Public PAIR website, Applicants can still use the Public PAIR website to order a copy of the provisional application. Whether the order for the provisional application copy is placed with the Office of Public Records directly from the Public PAIR website, or by mail (using Mail Stop Document Services), the order requires the fee under 37 C.F.R 1.19(b)(1).

The Office has reviewed the above-cited provisional applications and has confirmed that Doucette-Stamm *et al.* indeed disclosed a polypeptide comprising the IAQLAK sequence. Since the two provisional applications are very huge or voluminous and since the Office has terminated the practice of providing copies of such applications to Applicants, a copy of only the relevant page from the provisional application(s) containing the amino acid sequence that comprises the IAQLAK sequence is provided herein as an attachment to this Office Action. This attached page establishes that Doucette-Stamm *et al.* is entitled to a priority date earlier than the 30 June 1998 date. Therefore, Applicants' Rule 131 Declaration and the dateless Exhibit B do not overcome the

rejection of record.

Applicants' attention is drawn to the new art rejection set forth below which establishes that claim 1 is also anticipated by another prior art reference under 35 U.S.C. § 102(b).

Telephonic Interview dated 07/07/04

20) Applicants are asked to note the new art rejection made below in light of Applicants' statement made during the telephonic interview of 07/07/04 and/or Applicants' acknowledgement of Tsang's ('660) disclosure at lines 5-7 on page 3 of the instant specification. During the interview, Applicants stated that Tsang *et al.* ('660) have disclosed the 18 kDa larval *T. solium* polypeptide, but did not disclose the recombinantly produced 18 kDa polypeptide.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

21) The amended claims 23 and 29 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 23, as amended, and the new claim 29 encompass the polypeptide of SEQ ID NO: 4 comprising 'one or more' conservative substitutions and one or more non-conservative substitutions (hereafter referred to as 'polypeptide variants') respectively, wherein the polypeptide is 'immunoreactive with *T. solium* antibodies'. Applicants point to page 14, lines 1-6 and/or page 14, line 30- through line 4, page 15 for descriptive support for the claimed invention. However, these parts of the specification do not appear to provide descriptive support for a polypeptide of SEQ ID NO: 4 comprising one or more conservative or non-conservative amino acid substitutions and concurrently being 'immunoreactive with *T. solium* antibodies'. These parts of the specification do not support the limitation 'one or more' substitutions. Lines 1-5 on page 14 of the specification state that immunogenic peptides can be subject to various changes, such as insertions, deletions, and substitutions, either conservative or non-conservative, where such changes might provide for certain advantages in their use. Line 30 on page 14 through line 4 on page 15 of the specification describes conservative amino acid substitutions in 'one or a few' amino acids in an amino acid sequence of a protein, substituted with different amino acids with highly similar properties. However, this description for substituted proteins (i.e., variants) does not associate them with a specific function, such as, 'immunoreactivity with *T. solium* antibodies'. The specification and the claims, as

originally filed, are supportive of a composition comprising an isolated larval *T. solium* polypeptide comprising SEQ ID NO: 4, wherein the 'polypeptide or antigenic fragments thereof' are 'immunoreactive with *T. solium* antibodies'. Native polypeptides and antigenic fragments immunoreactive with *T. solium* antibodies are not the same as polypeptides comprising one or more conservative or non-conservative substitutions (i.e., polypeptide variants), which are immunoreactive with *T. solium* antibodies. The term 'more' in the limitation 'one or more' has no upper limit and causes the claim to include literally any number of substitutions, for which there is no descriptive support. The scope of the limitation 'one or a few' is not the same as the scope of the limitation 'one or more'. Therefore, the new limitations in the instant claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P. 608.04 to 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provides descriptive support for the claimed invention identified above, or to remove the new matter from the claims.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

22) Claims 1, 3, 5, 17-23, 27 and 29 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention.

(a) Claim 1 is vague and indefinite in reciting 'polypeptide comprising SEQ ID NO: ..' without particularly pointing out that the SEQ ID number represents the amino acid sequence. It is suggested that Applicants replace the recitation with --polypeptide comprising the amino acid sequence of SEQ ID NO: ..--.

(b) Claim 5 is indefinite and grammatically incorrect in the recitation 'a nucleic acid molecules comprising a nucleotide sequence'. For proper antecedence, clarity and correctness, it is suggested that Applicants replace the recitation with --a nucleic acid molecule comprising the nucleotide sequence--.

(c) Claim 3 lacks proper antecedent basis for the limitation: 'an amino acid sequence shown in SEQ ID NO: 4'. For proper antecedence and clarity, it is suggested that Applicants

replace the limitation with --the amino acid sequence of SEQ ID NO: 4--.

(d) Claim 29 lacks proper antecedent basis for the limitation: 'wherein SEQ ID NO: 4'. Claim 29 depends from claim 3, which already recites 'SEQ ID 4'. Therefore, for proper antecedence, it is suggested that Applicants replace the limitation with --the SEQ ID NO: 4--.

(e) Claim 27 is vague and indefinite in the recitation 'TS-18', because it is unclear what does it stand for. Is TS-18 an antigen, an epitope, a peptide, or a binding site which is comprised within the recited polypeptide?

(f) Claims 3, 5, 17-23, 27 and 29, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

23) Claims 1, 3, 5, 20 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tsang *et al.* (US 5,354,660 – Applicants' IDS) as evidenced by Applicants' admitted state of the prior art.

Tsang *et al.* ('660) disclosed a composition comprising the isolated or lectin-purified GP18 larval antigen of *T. solium* which is immunoreactive with *T. solium* antibodies, wherein the number is indicative of the molecular weight in K Daltons. The antigen is contained in a buffer or NaCl solution and has diagnostic use (see abstract; Figures 2 and 3; first, second and third full paragraphs in columns 2 and 3; and paragraph bridging columns 5 and 6). The isolated GP18 before undergoing lectin purification is expected to contain co-existing or contaminant proteins which serve inherently as carrier molecules. Tsang's isolated *Taenia solium* larval antigen, GP18, is viewed as the same as the instantly claimed TS-18, but identified by Applicants with the alternate designation of TS-18. Although Tsang *et al.* ('660) are silent about the sequence identifiers recited in the instant claims, Tsang's GP18 is viewed as structurally the same as the instantly claimed TS-18 based on the following overlapping facts or properties: (a) Tsang's ('660) GP18 has the same molecular weight of 18 kDa as that of the instantly claimed polypeptide ; (b) Tsang's ('660) GP18 is the larval antigen of *T. solium* immunoreactive with *T. solium* antibodies similar to the instantly claimed polypeptide; and (c) Applicants' admitted state of the prior art at lines 5-7 on page 3 of the instant specification that the US patent 5,354,660 issued to Tsang *et al.* describes purified, naturally-occurring *T. solium* larval glycoprotein, but not recombinantly produced antigen. Given the identical molecular weight of the prior art protein, the identical larval *T. solium* origin, and the

overlapping immunoreactivity with *T. solium* antibodies, the sequence identifiers recited in the instant claims are viewed as inherent elements of Tsang's ('660) protein, absent evidence to the contrary. Although Tsang *et al.* ('660) are silent about the sequence identifiers recited in the instant claims, the prior art GP18 is viewed as the same as the Applicants' TS-18 based upon the fact that every characteristic overlapping in Tsang's protein and Applicants' claimed invention are the same. There is sufficient overlap to reasonably conclude that Tsang's GP18 is one and the same as the Applicants' TS-18.

The term 'synthetic' or 'recombinant' in claim 1 represents a process limitation in a product claim. When claims are product-by-process claims, claims are not limited to the manipulations of the recited step(s), but only the structure implied by the steps. MPEP § 2113 states:

> [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)* (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. Applicants have not shown that the alleged difference(s) in the process results in a product that is structurally different from the product of the prior art. In the instant case, Applicants have not shown that the underlying structure of the prior art polypeptide differs from that of the instantly claimed polypeptide.

Claims 1, 3, 5, 20 and 27 are anticipated by Tsang *et al.* ('660).

24) Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Barrell *et al.*, or Murphy *et al.*, or de Virgilio *et al.* EMBL Z48612 (created 01 November 1996).

The transitional limitations 'having', 'comprising', 'including', 'containing', or 'characterized by', represent open-ended claim language and therefore, do not exclude additional, unrecited elements. See MPEP 2111.03 [R-1].

Barrell *et al.*, or Murphy *et al.*, or de Virgilio *et al.* disclosed an isolated polypeptide comprising the amino acid sequence, IAQLAK, i.e., the instantly claimed SEQ ID NO: 7. See the attached sequence search report which shows 100% sequence match between the prior art polypeptide and the instantly claimed SEQ ID NO: 7. That such a 6 amino acid-long polypeptide of SEQ ID NO: 7 is immunoreactive with *T. solium* antibodies is inherent from the teachings of the prior art, since such a polypeptide is well known in the art to be long enough to be antigenic being

capable of immunoreacting with a specific antibody. Although the prior art is silent about the immunoreactivity of their polypeptide, the prior art polypeptide is viewed as structurally the same as the Applicants' polypeptide. The Office's position that the prior art polypeptide is the same as the Applicants' polypeptide of SEQ ID NO: 7 is based upon the fact that every structural characteristic overlapping in the prior art polypeptide and the Applicants' disclosure are the same. In spite of the fact that the prior art fails to teach the disclosed functional characteristic of the Applicants' polypeptide, there is sufficient overlap to reasonably conclude that the prior art polypeptide is one and the same as the Applicants' polypeptide fragment. Since the prior art polypeptide is structurally the same as the polypeptide of SEQ ID NO: 7 recited in the instant claim, it is expected to have the ability to immunoreact with *T. solium* antibodies. The property of immunoreactivity with *T. solium* antibodies is viewed as an intrinsic function inseparable from the polypeptide of the prior art.

Claim 1 is anticipated by Barrell *et al.*, or Murphy *et al.*, or de Virgilio *et al.*

Rejection(s) under 35 U.S.C. § 103

25) Claims 17 and 20-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tsang *et al.* (US 5,354,660 – Applicants' IDS) ('660) as applied to claim 1 above and further in view of Campbell AM (*In*: *Monoclonal Antibody Technology*. Elsevier Science Publishers, The Netherlands, Chapter 1, pages 1-32, 1984, already of record).

The teachings of Tsang *et al.* ('660) are taught above, which do not disclose their composition further comprising an adjuvant or a carrier molecule, such as, BSA or KLH.

However, it was conventional and routine in the art to add an art-known adjuvant to an art-known polypeptide or peptide, or to link or conjugate it to an art-known carrier molecule, such as, BSA or KLH, to induce an enhanced antibody production to the polypeptide or peptide.

Campbell taught that it is customary now for any group working on a macromolecule to make antibodies to it sometimes without a clear objective for their application. Campbell also taught that protein macromolecules could be studied in the field of research using these antibodies (see page 29, last paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add an art-known adjuvant to, or link an art-known BSA or KLH carrier to Tsang's ('660) polypeptide to produce the instant invention with a reasonable expectation of

success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of using Tsang's ('660) polypeptide as an immunizing composition, since it is conventional in the art to add an art-known adjuvant or link an art-known carrier molecule to an art-known polypeptide or peptide to enhance antibody production to the polypeptide. One of skill in the art would have been motivated to generate high-titer antibodies or antisera to Tsang's ('660) polypeptide for the expected benefit of generating high-titer antibodies or antisera to Tsang's ('660) polypeptide in order to further study the polypeptide for research purposes as taught by Campbell.

Claims 17 and 20-22 are *prima facie* obvious over the prior art of record.

26) Claims 18 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tsang *et al.* (US 5,354,660 – Applicants' IDS) ('660) as applied to claim 1 above.

The teachings of Tsang *et al.* are explained above, which do not disclose their composition further comprising a label, such as, a radiolabel, fluorogen label, chromogen label, or bioluminescent label.

However, it was conventional and routine in the art to attach a chromogen label or a fluorogen label to an art-known polypeptide antigen known to have a diagnostic use.

Given the diagnostic use of Tsang's ('660) polypeptide, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to attach a chromogen label or a fluorogen label to Tsang's ('660) polypeptide to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to label Tsang's ('660) polypeptide for the expected benefit of producing a diagnostic reagent for the diagnosis of cysticercosis, or for commercializing Tsang's ('660) polypeptide for diagnostic purposes.

Claims 18 and 19 are *prima facie* obvious over the prior art of record.

Remarks

27) Claims 1, 3, 5, 17-23, 27 and 29 stand rejected.

28) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses and paper is (703) 872-9306.

29) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

30) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A telephone message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

November, 2004

S. DEVI, PH.D.
PRIMARY EXAMINER